

To the FDA:

I send this letter as a consumer of healthcare services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

The Memorandum of Understanding is a direct threat to the art of pharmacy compounding and is of concern to every consumer of healthcare services and products. The FDA is an agency of the U.S. Government that purports to be the "watchdog" for the consumer. However, as a governmental agency, the FDA also has a responsibility to be accountable to the people.

The MOU must be amended!!! In its present form, the MOU severely restricts my rights as an individual to obtain the healthcare services and products from the provider of my choice. The MOU should be amended so that there are no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel.

This is one of the very few sources for securing plant based feminine hormones - so we do not have to rely on pregnant mare's urine to formulate our hormones - as in the past.

Signed:

Therese Carroll Healer

State of Residence:

PA

Compound.

98N-1265

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9795 '99 MAR 18 10:15 Anne Carroll Nealis
817 Malin Road
Newtown Square PA 19073
March 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Women's International Pharmacy (5708 Monona Drive, Madison, WI 53716) is one of the few compounding pharmacies serving many menopausal women with individually compounded, natural hormone supplements.

As I understand the MOU, it would restrict me from having my physician prescribe what combination of natural hormones would best serve my health requirements during menopause. I have suffered many side effects, including abdominal pain severe enough to be hospitalized and tested for ulcers, from the use of manufactured hormones, in my case Premarin. Women's International Pharmacy and my MD have been invaluable in supporting me and my health through menopause and hopefully beyond.

Please review the Memo of Understanding and make the changes that will allow us to continue our successful relationship.

Sincerely,



Anne Carroll Nealis

cc: The Honorable Curt Weldon
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Washington DC 20515

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